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## 510(k) Summary (SMDA Summary)

## B. Braun Medical's Vena Tech LP Vena Cava Filter

**Submitter's Name and Address**

B. Braun Medical, Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
Phone: (610) 691.5400
Fax: (610) 691.6249

**Contact Person and Telephone/ Facsimile Numbers**

Paul O' Connell
Vice President, Vascular Products Group
2934 Central street 1A
Evanston, Illinois 60201
Tel. (847) 733.8900
Fax. (847) 733.1669

**Date Prepared:** February 17, 2001

**Name of Device and Name/ Address of Sponsor:**

Vena Tech LP Vena Cava Filter

B. Braun Medical, Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
Phone: (610) 691.5400
Fax: (610) 691.6249

**Common or Usual Name**

Vena Cava Filter

**Classification Name**

Cardiovascular Intravascular Filter

**Predicate Devices**

Vena Tech LGM Vena Cava Filter
Vena Tech LGM 30D vena cava filter

**Intended Use**

The Vena Tech LP Vena Cava Filter is designed for use as a permanently implanted Cardiovascular Intravascular filter and is intended to be used for partial interruption of the inferior vena cava to prevent Pulmonary Embolism as follows:

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- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

**Technological Characteristics and Substantial Equivalence**

Both the Vena Tech LGM and Vena Tech LP vena cava filters are permanently implanted vena cava filters designed to prevent pulmonary thromboembolism. Both filters are cone shaped, manufactured from Phynox, placed using a percutaneous, fluoroscopically guided insertion procedure, and consist of intraluminal filter elements meeting at an apex with stabilizing legs attached. Both filters are designed to capture potentially fatal blood clots while maintaining patency in the vena cava, preventing migration of emboli through the right heart and into the pulmonary circulation where they could block blood flow to all or part of the lung. The Vena Tech LP Vena Cava Filter is identical in intended use, materials and function and substantially equivalent in design to the currently marketed Vena Tech LGM Vena Cava Filter. Both the Vena Tech LGM vena cava filter and the Vena Tech LP vena cava filter have received the CE Mark, and both are in compliance with International Standard ISO 14630: "Non-active surgical implants – General requirements" and European Standard EN 12006-3 "Non active surgical implants – Particular requirements for cardiac and vascular implants – Part 3L Endovascular devices"

**Performance Data Summary**

The *in vitro* and *in vivo* testing performed on the Vena Tech LP vena cava filter have demonstrated that with regard to all pertinent functional and performance parameters, the Vena Tech LP filter is equivalent to the currently marketed Vena Tech LGM Vena Cava Filter. The use of Phynox wire in the Vena Tech LP Vena Cava Filter versus the Phynox plate utilized in the Vena Tech LGM Vena Cava Filter, offers no advantages or disadvantages in terms of filter function and performance, as demonstrated by all physical and animal tests. The Phynox wire composition of the Vena Tech LP Vena Cava Filter will allow the filter to be implanted using a smaller introducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Mr. Paul O'Connell
B. Braun Medical, Inc.
2934 Central Street, Suite 1A
Evanston, IL 60201

Re: K010485
Trade Name: Vena Tech LP Vena Cava Filter
Regulation Number: 870.3375
Regulatory Class: II (two)
Product Code: DTK
Dated: February 12, 2001
Received: February 20, 2001

Dear Mr. O'Connell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**



510(k) Number (if known): K010485

Device Name: Vena Tech LP vena cava filter

Indications For Use:

- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiov...
510(k) Number K010485